

the 12-month period that were conditioned upon the standard being met are overpayments.

(c) Once any group has chosen whether to use its fiscal year, the calendar year, or some other 12-month period, the group practice must adhere to this choice.

(d) The attestation must contain a statement that the information furnished in the attestation is true and accurate and must be signed by a group representative.

(e) A group that intends to meet the definition of a group practice in order to qualify for an exception described in §§411.355 through 411.357, must submit the attestation required by paragraph (a) or paragraph (b)(1) of this section, as applicable, to its carrier no later than 60 days after receipt of the attestation instructions from its carrier.

[60 FR 41978, Aug. 14, 1995, as amended at 60 FR 63440, Dec. 11, 1995]

#### §411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing items or services for which payment may be made under Medicare must submit information to HCFA concerning their financial relationships (as defined in paragraph (d) of this section), in such form, manner, and at such times as HCFA specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that provide 20 or fewer Part A and Part B items and services during a calendar year, or to designated health services provided outside the United States.

(c) *Required information.* The information submitted to HCFA under paragraph (a) of this section must include at least the following:

(1) The name and unique physician identification number (UPIN) of each physician who has a financial relationship with the entity;

(2) The name and UPIN of each physician who has an immediate relative (as defined in §411.351) who has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the

financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement, if requested by HCFA).

(d) *Reportable financial relationships.* For purposes of this section, a financial relationship is any ownership or investment interest or any compensation arrangement, as described in section 1877 of the Act.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information on a HCFA-prescribed form within the time period specified by the servicing carrier or intermediary. Entities are given at least 30 days from the date of the carrier's or intermediary's request to provide the initial information. Thereafter, an entity must provide updated information within 60 days from the date of any change in the submitted information. Entities must retain documentation sufficient to verify the information provided on the forms and, upon request, must make that documentation available to HCFA or the OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to \$10,000 for each day of the period beginning on the day following the applicable deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to HCFA under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

#### §411.370 Advisory opinions relating to physician referrals.

(a) *Period during which HCFA will accept requests.* The provisions of §§411.370 through 411.389 apply to requests for advisory opinions that are submitted to HCFA after November 3, 1997, and before August 21, 2000, and to any requests submitted during any other

time period during which HCFA is required by law to issue the advisory opinions described in this subpart.

(b) *Matters that qualify for advisory opinions and who may request one.* Any individual or entity may request a written advisory opinion from HCFA concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, HCFA determines whether a business arrangement described by the parties to that arrangement appears to constitute a "financial relationship" (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral prohibition described in section 1877 of the Act.

(1) The request must involve an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. HCFA does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) *Matters not subject to advisory opinions.* HCFA does not address through the advisory opinion process—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) *Facts subject to advisory opinions.* HCFA considers requests for advisory opinions that involve applying specific facts to the subject matter described in paragraph (b) of this section. Requestors must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in §411.372.

(e) *Requests that will not be accepted.* HCFA does not accept an advisory opinion request or issue an advisory opinion if—

(1) The request is not related to a named individual or entity;

(2) HCFA is aware that the same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) HCFA believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

(f) *Effects of an advisory opinion on other Governmental authority.* Nothing in this part limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other agency of the Government. In addition, in connection with any request for an advisory opinion, HCFA, the OIG, or the Department of Justice may conduct whatever independent investigation it believes appropriate.

[63 FR 1655, Jan. 9, 1998]

#### **§411.372 Procedure for submitting a request.**

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to HCFA in writing, including an original request and 2 copies. The request must be addressed to: Health Care Financing Administration, Department of Health and Human Services, Attention: Advisory Opinions, P.O. Box 26505, Baltimore, MD 21207.

(b) *Information HCFA requires with all submissions.* The request must include the following:

(1) The name, address, telephone number, and Taxpayer Identification Number of the requestor.

(2) The names and addresses, to the extent known, of all other actual and potential parties to the arrangement that is the subject of the request.

(3) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with HCFA on behalf of the requestor.